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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,400	04/07/2006	Jouko Savolainen	LOYZ 2 00005	8987

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
10/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,400	SAVOLAINEN ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,11,14-16,18-22,25,26,30,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,11,14-16,18-22,25,26,30,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2008 has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 3, 6-10, 12-13, 17, 23-24, 27-29, 31-32 are canceled. Claims 1-2, 4-5, 11, 14-16, 18-22, 25-26, 30, 33-34 are currently under examination.

Priority: The request for priority to FINLAND 20031506, filed October 15, 2003, and FINLAND 20031508, filed October 15, 2003, is acknowledged.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-5, 11, 14-16, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krochta et al. (US 5543164; previously cited) in view of Mangino et al. (1984 J Dairy Science 67: 2711-2722). Krochta et al. ('164) disclose water-insoluble protein-based

coatings and films and methods for their preparation (col. 4 lines 33-35). Krochta et al. disclose the first step is the formation of an aqueous denatured protein solution (col. 5 lines 12-13). Preferred proteins include whey protein (col. 5 lines 22-23, col. 8). The thiol-disulfide exchange can be effected by a chemical treatment or an enzymatic treatment (col. 5 lines 25-26). When a chemical treatment is used, the protein is brought into contact with a chemical agent for a period of time sufficient to initiate disulfide arrangements, wherein the chemical agents include sulfites (col. 5 lines 37-43). Further, thiol-disulfide exchange in a protein can also be performed enzymatically (col. 5 lines 47-48). Following disulfide bonds and thiol-disulfide interchange, any remaining free thiol groups can be oxidized (col. 5 lines 44-46), which would indicate that free thiol groups can be present on the whey proteins upon gelation and/or formation into a film. The result of these reactions is a solution of a denatured protein having a mixture of intermolecular and intramolecular disulfide crosslinks (col. 5 lines 51-53), which is used to form a coating and/or film. Krochta et al. do not teach from about 2 to about 4 free sulfhydryl groups per protein.

Mangino discloses physical and chemical properties of whey protein. Mangino discloses that whey protein gels can be obtained by heating (p. 2714 col. 2). Mangino further discloses that free sulfhydryl groups have a significant effect on properties of whey protein gels (p. 2716 col. 1). At low concentrations, gel strength increases as free sulfhydryl group increases. At some maximal concentration, also depending on pH, ionic strength, and calcium content of the system, gel strength begins to decrease with further increases of free sulfhydryls (p. 2716 col.1). Beyond a certain concentration, free sulfhydryl groups probably inhibit formation of disulfide linkages and thus weaken gel structure (p. 2716 col. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a whey protein-based film by chemical and/or enzymatic treatment according to the teachings of Krochta et al. ('164) and adjust the number of free sulfhydryl groups present per protein in said film, as suggested by Mangino, so that an appropriate concentration of free sulfhydryl groups (i.e. about 2 to about 4 free sulfhydryl groups per protein) can be obtained in order to create a film that has optimum strength and/or elasticity (claims 1-2, 4-5, 11, 14-16, 18-19). The motivation to do so is given by Mangino, which disclose that free sulfhydryl groups have a significant effect on properties of whey protein gels. As previously noted, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."; In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). In this instance, since Krochta '164 discloses the presence of free sulfhydryl groups and Mangino discloses that gel strength is related to the concentration of free sulfhydryl groups, as well as suggest that beyond a certain concentration, free sulfhydryl groups will weaken gel structure, it would be reasonable for one of ordinary skill to determine the ideal concentration of free sulfhydryl groups that should be present to create a gel or film with the optimum strength and/or elasticity.

Krochta et al. ('164) also disclose that said protein-based film can be formed on a food item (col. 5 lines 55-60), and can be formed around a lipid (col. 6 lines 7-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the protein-based film of Krochta et al. ('164) in view of Mangino on a food item, edible product, and/or any other type of appropriate product because Krochta et al. ('164) suggest that an edible protein-based coating can be used to coat foodstuff to make it more appealing or to protect it from moisture (claims 11, 14-16, 18-19).

Claims 20-22, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krochta et al. (US 5543164; previously cited) in view of Mangino et al. (1984 J Dairy Science 67: 2711-2722) in view of Shimada et al. (1988 J Agric Food Chem 36(5): 1018-1025). The teachings of Krochta et al. in view of Mangino et al. are outlined above. Neither Krochta et al. nor Mangino teach a pH of 7.

Shimada et al. disclose gel texture (firmness, elasticity) are correlated with free sulfhydryl groups present (p. 1018). Shimada et al. disclose the influence of pH on the characteristics of whey protein gels, i.e. the total SH group content decreases in gels of increasing pH (p. 1021 col. 2). Shimada et al. further disclose that low SH reactivity at acid pHs prevents SH/S-S interchange reactions, resulting in gels with low elasticity and high protein solubility (p. 1021 col. 2). At neutral pHs, intermolecular SH/S-S interchange reactions are enhanced, leading to elastic gels with lower protein solubility. At pH $\geq$ 8.5, gels have reduced firmness and enhanced protein solubility (p. 1021 col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the chemical treatment of the thiol-disulfide exchange of Mangino et al. at the pH of 7.0 as suggested by Shimada et al. because Shimada et al. disclose that a pH of 7.0

enhances intermolecular SH/S-S interchange reactions, resulting in an elastic gel (claims 20-22, 25-26). Regarding the concentrations recited in claims 22 and 25, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."; In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). In this instance, it would be reasonable for one of ordinary skill to arrive at the optimum combination of free sulfhydryl group content and sulfite concentration.

Krochta et al. ('164) also disclose that said protein-based film can be formed on a food item (col. 5 lines 55-60), and can be formed around a lipid (col. 6 lines 7-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the protein-based film of Krochta et al. ('164) in view of Mangino in view of Shimada et al. on a food item, edible product, and/or any other type of appropriate product because Krochta et al. ('164) suggest that an edible protein-based coating can be used to coat foodstuff to make it more appealing or to protect it from moisture (claims 30, 33-34).

In their remarks, Applicants assert the cited references do not suggest that the elasticity of a protein network is related to the number of free sulfhydryl groups present. Instead, they suggest that the elasticity is related to the number and character of disulfide bonds. Of particular importance to Applicants' arguments is the fact that the number of disulfide bonds present is not the same thing as the number of free sulfhydryl (i.e. thiol) groups present. (1) Krochta et al. '164

discloses heating a protein solution to initiate SH/S-S interchange reactions and SH oxidation reactions; see column 5, lines 5-43. Please note that in an SH-S-S interchange reaction, the number of thiol groups does not change. Applicants do not find any passages in Krochta et al. '164 or Krochta '628 that suggest increasing the number of free SH groups is desirable. (2) Applicants disagree that one of ordinary skill would recognize that the number of free sufhydryl groups can be adjusted accordingly in the protein network of Krochta et al. '164 in view of Krochta '628. Applicants assert that the number of intermolecular S-S bonds and the number of free SH groups are not related to each other. (3) Regarding claim 20, Applicants submit that it would not be reasonable to correlate chemical treatment conditions with enzymatic treatment conditions. Applicant's arguments have been fully considered but they are not persuasive.

(1) The Krochta '628 (US 6869628) reference has been withdrawn and replaced by the Mangino reference. The Krochta et al. '164 reference is maintained in view of Mangino. As noted in the previous Office action, in col. 5, lines 44-48, Krochta et al. '164 disclose that the remaining free thiol groups can be oxidized by exposure to atmospheric oxygen or by reaction with oxidizing agents. It should be noted that Krochta et al. '164 do not disclose that said remaining free thiol groups should be oxidized. The Mangino reference discloses that gel strength and/or elasticity is correlated with free sulfhydryl groups. Therefore, it would be reasonable for one of ordinary skill to recognize that while Krochta et al. '164 suggest that the remaining free thiol groups can be oxidized, Krochta et al. '164 do not necessarily teach that they have to be oxidized and since it is known in the art that gel strength is correlated with the number of free sulfhydryl groups (as disclosed by Mangino), it would be reasonable for one of ordinary

skill to have the motivation to discover the optimum concentration of free sulfhydryl groups that correlates with the ideal gel strength.

(2) Regarding Applicants' assertion that the number of intermolecular S-S bonds and the number of free SH groups are not related to each other, it should be noted that while the total number of free SH groups will not change during a SH/S-S interchange reaction, the free SH groups that appear will be relocated from protein to protein. This is noted by the previously cited 1989 Shimada reference (Shimada et al. 1989 J Agric Food Chem 37: 161-168), which disclose that new SH groups are formed in a SH/S-S interchange reaction (p. 161). Therefore, since Krochta '164 disclose the presence of free sulfhydryl groups and Mangino discloses that gel strength is related to the concentration of free sulfhydryl groups, as well as suggest that beyond a certain concentration, free sulfhydryl groups will weaken gel structure, it would be reasonable for one of ordinary skill to determine the ideal concentration of free sulfhydryl groups that should be present to create a gel or film with the optimum strength and/or elasticity.

(3) Regarding the pH of 7.0 recited in instant claim 20, this limitation is believed to be met by the newly cited 1988 Shimada et al. reference.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

October 8, 2008